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A novel HIV treatment model using private practitioners in South Africa

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Abstract

Objectives—The extent of the HIV epidemic in South Africa may render the public sector capacity inadequate to manage all patients requiring antiretroviral therapy (ART). Private practitioners are an underutilised resource that could be utilized to ease this challenge.

Methods—We developed a model of care using 72 private practitioners in five provinces in urban and rural areas of South Africa with centralised clinical support, training, pharmacy control and data management. We describe the programme, its quality control measures and patient outcomes using a cohort analysis.

Results—Between January 2005 and December 2008, 9,102 individuals were started on ART, 63% female, mean age 35 years, median viral load 50,655 copies/ml and median baseline CD4 count 123 cells/μl. Retention (alive and in care) in those who started on ART after 12 months was 63% (5,743/9,102) in the 2005 cohort and did not change by calendar year. After 36 months, retention was 50% and 59%, for those enrolled in 2005 and 2006 respectively. The percentage virally suppressed remained similar over the cohorts at 6 months, 82% vs. 84%, 84% and 85% from 2005 - 2008, p=0.66; but improved slightly at 12 months, 78% vs. 83%, 83% and 84% from 2005 - 2008, p=0.05.

Conclusions—The results show that a well-managed private practitioner-based model can achieve comparable results to public service programmes, although long-term retention needs further evaluation. This model of ART delivery can be used to expand access to ART in areas where the public sector is unable to meet the demand.

Introduction

Despite recent international efforts to scale-up antiretroviral treatment (ART), by the end of 2009, only 36% of those in need of ART worldwide were receiving treatment (based on WHO 2010 guidelines, starting ART at CD4<350) [1, 2]. In South Africa, limited human

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Competing interests
There are no competing interests to declare.

resource capacity within the public health sector is one of the main constraints to achieving universal ART coverage[2]. Problems include insufficient numbers of trained health workers, illness and emigration, in addition to rising demand for treatment [3, 4]. Models have predicted that in Southern Africa, around three times the current number of health workers will be needed by 2017 to provide ART to those who require it[5]. Innovative solutions are needed to address the shortfall in capacity.

Private practitioners play a key role in health care delivery in many settings, including South Africa, presenting an opportunity to expand ART care capacity. However, South African studies [6, 7] evaluating quality of treatment for sexually transmitted infections amongst private practitioners raised concerns about knowledge and practice of private practitioners. Another small study in India [8] which evaluated management of malaria in private practitioners, found that malaria management was generally poor and that national guidelines were not adhered to. These have led to reluctance in considering this model of care for providing ART in South Africa. In this paper we describe the feasibility of implementing a model of provision of ART through private practitioners and the main programme outcomes of retention in care and virological suppression.

Methods

We developed a model for HIV care (including ART provision) using private practitioners with donor funding (President's Emergency Plan for AIDS Relief), starting in January 2005. The private practitioner programme design was based on a workplace programme managed by the Aurum Institute that has been described previously [9, 10]. The private practitioner model of ART delivery is a centrally-managed programme which includes HIV specialist support, HIV training, data management, laboratory and pharmaceutical services. Treatment regimens and initiation criteria for provision of ART were in accord with South African national guidelines.

Site eligibility

Medical doctors in private practice were eligible to join the private practitioner programme if they were registered with the national health professions council. In addition, the provider had to identify a nurse who would provide counselling and administrative support, and a site assessment visit was conducted to ensure facilities were appropriate for the programme implementation. Both the nurse and the provider were required to attend training (as described below) before the site could be initiated. Once all other criteria had been fulfilled, a site initiation visit was conducted for provision of administrative materials such as patient files, guideline documents and data collection tools.

Training

Doctors involved in the programme were required to attend a three-day HIV/AIDS management training course (available nationally at regular intervals) and a two-day clinical training course (provided by the Aurum Institute) which included ART regimens, adherence, adverse events and their management, changing treatment regimens, ART for children and tuberculosis (TB) treatment. Nurses attended a two-day training course which included ART regimens, adherence, adverse events and their management, changing treatment regimens, ART for children and TB treatment.

In addition, each private practitioner site was encouraged to send at least one professional nurse or lay counsellor (where a private practitioner employed lay counsellors) for training in advanced patient counselling such as ART adherence counselling, running support

groups, reducing stigma and enhancing disclosure, and ART adherence counselling for children.

Clinical care

Patients were eligible to join the private practitioner programme and receive free of charge HIV-related medical care, if they earned less than R5,000 (±£400) per month or R60,000 ((± £4,800) per year and were not covered by medical insurance. The initial visit included a CD4 count and screening for TB disease with a symptom screen and chest radiograph. Any patient suspected of having TB was referred for sputum examination at the nearest government clinic. Eligibility to start ART was according to South African national guidelines (which was, during the period described in this paper, CD4 count below 200cells/μl or WHO stage IV). First-line ART consisted of two nucleoside reverse transcriptase inhibitors (stavudine and lamivudine) and one non-nucleoside reverse transcriptase inhibitor (efavirenz). In women of child-bearing potential, nevirapine was usually used in place of efavirenz. The second line regimen was zidovudine, didanosine and lopinavir-ritonavir.

The private practitioner sites adhered to a standard schedule of follow-up visits, laboratory testing, and administrative tasks with clinic visits at weeks 2 and 6, and months 3, 6, 9 and 12. Routine laboratory testing included full blood count, serum HIV RNA, and CD4 lymphocyte count at baseline, 6 weeks and 6 months and six-monthly thereafter. At each ART visit, patients received adherence counselling from a nurse or a lay counsellor based on a four-stage adherence counselling model[11]. Medications were dispensed monthly to a patient at the clinic site based on a medication script that was valid for six months.

Ensuring quality care

Once the programme was initiated, a number of activities ensured adherence to guidelines and high quality care. Experienced HIV clinicians were responsible for the initial training of the doctors, and were available via a 24-hour telephone line to answer clinical queries. In addition, these clinicians authorised all medication scripts before the centralised pharmacy was permitted to dispense the medication. Each site was allocated a monitor with a nursing background who was responsible for providing programmatic support. Monitoring site visits were conducted at least every three months. The monitor liaised between the site and the laboratory and pharmacy, ensured that data entry onto the data forms was correct and complete, and audited a sample of patient files for adherence to protocols. Sites were only allowed to enrol new patients if the monitoring report indicated that they were meeting the required standard of patient care.

Financial support

Each site was remunerated on a per-patient per-month basis to cover the private practitioner and nurse costs, counselling of patients, and overheads. The reimbursement per ART patient in their first year on the programme was around $35/month and was based on time and motion studies done in other settings and average salaries for the professional staff. Payments were made after receipt of patient visit forms from private practitioner sites. Each private practitioner was required to produce evidence of continued attendance of patients in order to receive the per-patient reimbursement. Drug and laboratory costs were paid directly to the central pharmacy and clinical laboratory used for all patients on the programme.

Data collection

Clinical data were collected on standardised forms which were faxed or couriered to the central data management centre. The data were entered into a relational database by trained

data capturers. Unique clinic numbers, rather than names, were used to identify patients. Clinical data were integrated with laboratory electronic records.

Data analysis

We evaluated patients starting ART within the programme from 1 January 2005 to 31 December 2008 and followed patients until 31st December 2009. WHO stage at ART initiation was obtained from provider reports. CD4 count measured 180 days before and up to 15 days after starting ART, and viral loads 180 days before and 5 days after, were considered to be baseline measurements. For the purposes of this analysis, retention was defined as "patients alive and in care at the end of a period". The two most common reasons for losses were 1) death of the patient, 2) "loss to follow-up". Death was ascertained by report from the clinical site or through linkage of identity numbers with the South African death registry. "Loss to follow-up" was defined as those patients who had not presented for 6 months after the last visit and were not known to have died. Virologic suppression, reported only among those with an HIV RNA result, was defined as an HIV RNA <400 c/mL to avoid considering virologic "blips" as failure and for comparability with prior reports. In order to describe programme performance over calendar time, programme outcomes were determined for sequential cohorts of patients starting ART in each calendar year period. Retention outcomes are reported using all individuals in each calendar year cohort as the denominator.

Ethical considerations

This study was approved by the research ethics committees of the University of KwaZulu-Natal, South Africa, and the London School of Hygiene and Tropical Medicine, United Kingdom.

Results

From March 2005 to December 2008, 72 sites took part in the programme. These sites were mainly in four provinces in South Africa (Gauteng, Limpopo, North West and Free State). A total of 15,365 patients enrolled into HIV care by end 2008, of whom 9,102 (59%) started ART, which was a median of 111 (IQR: 83-242) patients per site. Funding constraints restricted enrolment of patients in 2008 (Figure 1). Of the 9,102 patients enrolled on ART, 62% were female, the median age was 34 years (IQR 29-41), the baseline median CD4 count was 123 (IQR: 52-197), the median viral load was 50,655 copies/ml and 57% of patients were WHO stage 3 or 4 (Table 1). Median time from the first visit to starting on ART for patients who presented with CD4 less than 200 at their first visit to the clnic (n=5,384) was 10 days (IQR: 0-22). Furthermore of those started on ART, 7,773/9,102 patients (85%) started co-trimoxazole preventive therapy and 860/9,102 eligible patients (9%) started isoniazid preventive therapy.

Of all 9,102 initiators, by the end of the study period (maximum of 60 months), 4,663(51%) patients had left the programme, of which 1395 (15%) had died, 1966 (22%) were lost to follow-up and 1302 stopped for other reasons including adverse effects, patient requests and transfers due to relocation. The proportion of patients with virological suppression, among those with an available viral load result at each time point, was 3,439/4,087 (84%) at 6 months; 3,736/4,540 (82%) at 12 months; 2,440/2,945 (83%) at 24 months and 1,266/1,543 (82%) at 36 months.

Treatment outcomes of cohorts of patients started on ART in each calendar year are summarised in Table 2. The median CD4 count at baseline increased from 105 cells/μl in 2005 to 157 cells/μl in 2008 ($p_{trend}{}^{1}$<0.001). Comparing attrition at 12 months over the

cohorts, overall attrition remained similar from 380/1,024 (37%) in 2005 to 789/2,197 (36%) in 2008. After 36 months, retention was 50% and 59%, for those enrolled in 2005 and 2006 respectively. Among those retained in care, the percentage with virological suppression by 6 months remained similar over time (2005:82%, 2006:84%, 2007:84% and 2008:85%, p=0.66) but virological suppression at 12 months has improved slightly from 78% in 2005 to 83%, 83% and 84% in 2006, 2007 and 2008 respectively (p=0.05, p_{trend} =0.018).

Discussion

Our experience with a large and diverse private practitioner programme supports the feasibility of this model to rapidly scale-up provision of high-quality HIV care to a large number of patients and to achieve acceptable results. This private practitioner programme provides a viable and effective approach to increasing access to antiretroviral therapy in areas where public sector programmes have reached or exceeded capacity. This may prove valuable as the current treatment needs increase over the next years.

The advantages of the private practitioner model include the speed of scale up of the programme: very little preparation time is needed since the model uses existing staff and infrastructure, and private practitioners already have a pool of patients who require treatment. In patients who were eligible for ART at their first visit, treatment was started in most cases within three weeks of presentation, reflecting the efficiency of the programme.

The proportion of patients virologically suppressed at 12 months in our study (82%) is similar to another ART programme using private practitioners in a rural clinic in South Africa (81%)[12] and to that reported in a systematic review of 89 antiretroviral therapy programmes in sub-Saharan Africa (76%)[13] and better than that reported in a fee for service private practitioner programme in Kenya (47%)[14]. The results from our programme are also similar to those seen in well-established NGO and public sector ART programmes in resource-limited settings. This demonstrates an overall success in achieving results as good as seen in dedicated HIV clinics in the public sector.

Overall patient attrition in our programme was higher than reported in a systematic review where median attrition (including deaths) at 12, 24 and 36 months was 22.6% (range 7%–45%), 25% (range 11%–32%) and 29.5% (range 13%–36.1%) respectively[15]. The difficulty in comparing with the systematic review is that definitions of loss to follow up varied or were not reported[15], and attrition was comprised of a mixed group of outcomes, including deaths. Results from an ART programme in Cape Town, South Africa, shows that without death registry information, deaths are under-ascertained and loss to follow up is overestimated [16, 17]. The use of the death registry to distinguish between deaths and loss to follow-up is therefore a strength of this study. Reasons for the high attrition rate in our study are not known but are thought to be a combination of high patient movement away from these areas, as well as self-transfer of patients to other facilities. An in-depth investigation of these losses is currently underway and a formal process of tracking is also being implemented.

A disadvantage of this private practitioner model is that care involves medical doctors, which may be considered inefficient when such care can be delivered by nurses. However patient reluctance to use public health facilities is well known in South Africa, where 21% of the population use the private sector on an out-of-pocket basis for primary care level care but are then dependent on the public sector for hospital care[18]. Although density ratios for medical practitioners and nurses within South Africa are above minimum levels proposed by

[1]P for linear trend

the World Health Organisation (230:100 000), there are still drastic shortages in public sector and rural areas[19], and the increased strain on the public health system due to the AIDS pandemic has resulted in severe human resource shortages, with an estimated shortage of 80,000 total health workers in 2009[19].

A general reluctance to include private practitioners in ART delivery has originated from the perceptions that private practitioners would not follow treatment guidelines or be willing to collect data. Our experience shows that in a well-controlled environment with sufficient training and monitoring, it is possible to achieve acceptable results. Measures that were put in place included control of prescriptions, contracting of private practitioners and regular monitoring of the programme. If such a programme were to be implemented, measures such as these would need to be implemented.

One of the biggest challenges of the programme has been ensuring prompt payment of practitioners. Payment occurs only on receipt of patient data and requires data entry before payment approval is given. We have implemented an electronic submission system that allows for faster claims from private practitioners and ensures more rapid payments. Another challenge was the management of patients with adverse effects and opportunistic infections as this aspect was not funded by our programme. Patients were either referred to public facilities for further management or self-funded this aspect of care. Implementation of private practitioner programmes should include funding to cover management of adverse effects and limited care of opportunistic infections to avoid interruption in care.

A challenge experienced by private practitioners was the overwhelming demand for ART from their patients. Despite the success of the private practitioner programme in rapid scale up to deliver HIV care to large numbers of patients, funding was curtailed owing to concerns that the private practitioner model of ART delivery was unsustainable. Clearly, even with satisfactory outcomes and acceptance among private practitioners, the use of private practitioners needs to be justified from an economic perspective as well. We did not include a cost comparison exercise here.

Given the shortage of skills in the public sector in South Africa, the private practitioner model merits consideration as a complementary model of ART delivery in South Africa. Our results show that a well-managed private-based model can achieve acceptable adherence and virological outcomes. Retention in this programme was an issue and this would need to be investigated further to determine causes of the high attrition rate. This model of a private practitioner-provided HIV care service can be used to expand ART delivery in areas where there is high demand, and where the public sector is unable to meet the demand entirely.

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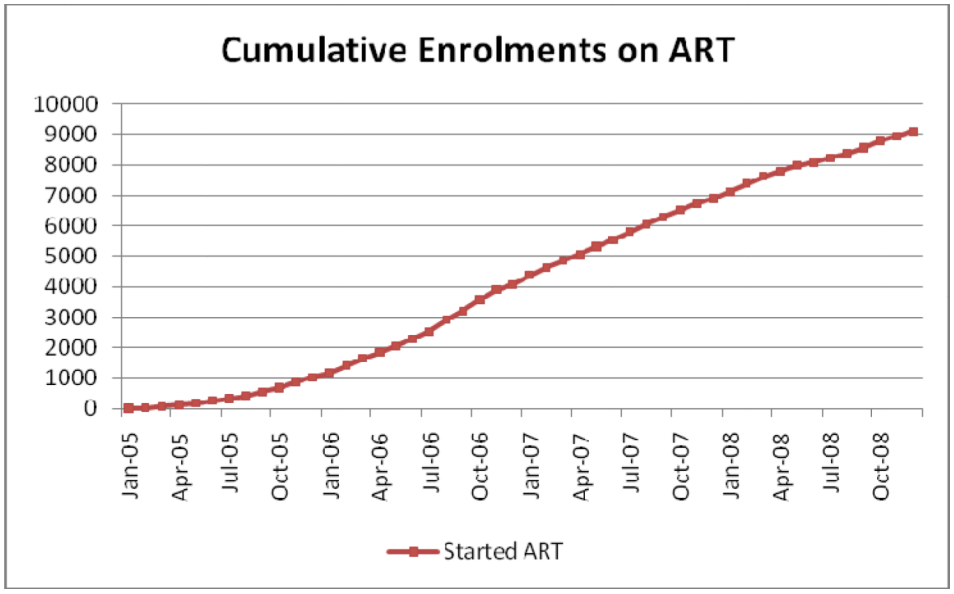

Figure 1.
Cumulative enrolment of patients

Table 1

Baseline characteristics of patients starting antiretroviral therapy

Characteristic	Total number (N=9,102)	%
Gender		
Male	3,475	(38)
Female	5,627	(62)
Age Groups (years)		
<18	295	(3)
18 – 29	1,819	(20)
30 - 39	4,041	(44)
40 – 49	2,131	(23)
50 – 59	689	(8)
60 or greater	127	(1)
CD4 count (cells/μL)[1]		
<50	1,826	(24)
51–200	3,876	(52)
201–350	1,174	(16)
351–500	324	(4)
> 500	303	(4)
Viral load (copies/ml)[2]		
Median (IQR)	50,655	(8,202-168,933)
< 10,000	1,770	(27)
10,000-100,000	2,462	(37)
>100,000	2,381	(36)
WHO* stage at start		
1	3,144	(35)
2	741	(8)
3	2,252	(25)
4	2,965	(32)

IQR = interquartile range

*World Health Organization stage

[1]N=1599 missing

[2]N=2489 missing

Table 2

Antiretroviral therapy start year cohort analysis of patients on the private practitioner programme

	Cohort 1 2005	Cohort 2 2006	Cohort 3 2007	Cohort 4 2008	P-value*
Number of patients	1,026	3,065	2,815	2,196	
First-line regimen (%)	966 (94)	2,994 (98)	2,752 (98)	2,168 (99)	
Median CD4 at ART start	105	110	132	157	<0.001
Median CD4 6 weeks [change from baseline]	200 [80]	210 [84]	207 [68]	233 [81]	<0.001
Median CD4 6 months [change from baseline]	245 [106]	230 [102]	248 [98]	283 [102]	<0.001
Median CD4 12 months [change from baseline]	280 [156]	271 [141]	287 [138]	300 [140]	<0.001
Median CD4 24 months [change from baseline]	374 [226]	357 [217]	364 [206]	379 [173]	0.51
Median CD4 36 months [change from baseline]	447 [306]	399 [264]	401 [266]	-	0.01
>1 log VL drop at 6w (%)	361/431 (84)	1,079/1,279 (84)	784/922 (79)	364/474 (77)	<0.001
VL < 400 at 6m (%)	410/498 (82)	1,123/1,334 (84)	1,063/1,261 (84)	843/994 (85)	0.66
VL < 400 at 12m (%)	442/565 (78)	1,208/1,464 (83)	1,200/1,453 (83)	886/1,058 (84)	0.05
VL < 400 at 24m (%)	398/474 (84)	988/1,194 (83)	988/1,198 (82)	-	0.90
VL < 400 at 36m (%)	344/421 (84)	851/1,038 (82)	-	-	0.27
Total losses by 6m (%)	135 (13)	412 (13)	305 (11)	170 (8)	<0.001
Total losses by 12m (%)	380 (37)	1,285 (42)	905 (32)	789 (36)	<0.001
Lost to follow up by 12m (%)	96 (9)	435 (14)	306 (11)	430 (20)	
Deaths by 12m (%)	144 (14)	461 (15)	327 (12)	214 (10)	
Transferred by 12m (%)	67 (7)	77 (3)	16 (1)	31 (1)	
Other**	73 (7)	312 (10)	256 (9)	114 (5)	
Total losses by 24m (%)	467 (46)	1,577 (51)	1,299 (46)	-	<0.001
Total losses by 36m (%)	514 (50)	1,818 (59)	-	-	<0.001
Second-line regimen (%)	60 (6)	71 (2)	63 (2)	28 (1)	

*Pearsons chi-squared test for all categorical variables and Kruskal-Wallis test for all continuous variables

**The other category includes stops due to adverse events, patient requests and other non-specified reasons.